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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Dennis S. Fernandez

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FERNANDEZ & ASSOCIATES, LLP  
P.O. BOX D  
MENLO PARK, CA 94026

EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/646,682	FERNANDEZ, DENNIS S.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ERIC S. DEJONG	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-49 and 51-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED OFFICE ACTION

Applicants response filed 10/05/2009 is acknowledged.

Claims 1-35 are cancelled. Claims 36-55 are pending. Claim 50 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/15/2008. Claims 36-49 and 51-55 are currently under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-49 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is necessitated by amendments made to the instant claims.

In the instant case, independent claims have been amended so as to recite a systems-biology platform comprising “computational modeling hardware and software genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, and transcriptomics” in independent claims 36 and 40. Further, it is noted that applicants did not cite any support for the instant amendment from the instant specification. Upon review of the instant disclosure, the examiner is unable to find any support disclosure in the instant specification for said amendments. Therefore, applicants amendment is considered new matter.

### ***Response to Arguments***

Applicant's arguments filed 10/05/2009 have been fully considered but they are not persuasive.

Applicants argument regarding the rejection of claims under 35 USC 112, 2<sup>nd</sup> indicated Figure 3a as support for “computational modeling hardware and software analysis”, genomics proteomics (paragraph 124), computational chemistry (paragraph 125), pharmacogenomics (paragraph 126), cell behavior (paragraph 127), pharmacokinetics (paragraph 128), metabolomics (paragraph 129), and transcriptomics (paragraph 130), and further descriptions provided on pages 36-38.

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In response, it is first noted that applicants have not provided any support for either of the “computational biology” or “computational biophysics” species recited in the instant claim. This alone demonstrates that applicants do not have sufficient written support from the instant specification for the above cited amendment. Further, the support cited by applicant merely is a reiteration of the terms recited in the instant claims does not contain any further description on the actual elements that comprise the “computer modeling hardware and software” as instantly claimed. Such does not amount to any meaningful definition. Thus the instantly claimed limitation of “computer modeling or hardware and software” is undefined and unbounded as it is only limited to broad field of use language and not particular language that identifies actual, meaningful elements that limit the scope of the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-49 and 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims have been amended so as to recite a systems-biology platform comprising “computational modeling hardware and software analysis genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics,

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metabolomics, and transcriptomics" in independent claims 36 and 40. However, this causes the metes and bounds of the instant claims to be indefinite because it cannot be determined what, if any, structural or functional limitations are imposed upon the "systems-biology platform". As amended, the instant claims now recite the nonse terms "computational modeling hardware and software analysis genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, and transcriptomics" appears to represent some sort of computational device directed to the generic fields of use specified in the instant claim, specifically the fields of "genomics", "proteomics", "computational chemistry", "pharmacogenomics", "computational biology", "computational biophysics", "computational cell behavior", "pharmacokinetics", "metabolomics", and "transcriptomics". See the precedential BPAI decision Ex parte Rodriguez (2009). As indicated in the rejection of claims under 35 USC 112, 1<sup>st</sup> for introducing new matter, the instant specification does not describe nor teach any particular computational device that sufficiently describes what the claimed "computational modeling hardware and software analysis genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, and transcriptomics" actually comprises as far as components and programming is concerned. Therefore, the instant claims remain indefinite because the scope of the instantly claimed "computational modeling hardware and software" is not defined in either the claims nor the instant specification.

For the purpose of continuing examination and consideration of prior art, the recitation of a systems-biology platform comprising “computational modeling hardware and software genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, and transcriptomics” has not been afforded weight because it does not serve to place any meaningful limit on a “systems-biology platform” as instantly claimed.

### ***Response to Arguments***

Applicant's arguments filed 10/05/2009 have been fully considered but they are not persuasive.

Applicants argue that the instant claims now recite “computational modeling hardware and software” and therefore the claims are not limited to abstract fields of analysis.

In response, it is reiterated that the support cited by applicant merely is a reiteration of the terms recited in the instant claims does not contain any further description on the actual elements that comprise the “computer modeling hardware and software” as instantly claimed. Such does not amount to any meaningful definition. Thus the instantly claimed limitation of "computer modeling or hardware and software" is undefined and unbounded as it is only limited to broad field of use language and not particular language that identifies actual, meaningful elements that limit the scope of the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-49 and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porat et al. (US Patent No. 6,432,050) in view of Giuffre (US Patent No. 6,024,548).

The instant claims are drawn to an integrated biosensor and simulation system and method of use. The system comprises an implantable biosensor, and a simulator comprising a systems-biology platform for generating a therapeutic or diagnostic output, wherein said simulator is reconfigurable by said simulator, such reconfiguration thereby reconfiguring a biocatalyst chip, a logic device, a tissue scaffold, a therapeutic reservoir, or a DNA microarray. The related method of use comprises the steps of sensing a biological target to generate a signal, simulating using said signal and a model of the biological target to generate a therapeutic or diagnostic output.

Porat et al. sets forth systems and methods of use for an implantable biosensor system for monitoring and optionally alleviating a physiological condition in a patient (see Porat et al., Abstract and throughout). Porat et al. further teaches that the implantable biosensor is used to generate a signal comprising information pertaining to a patient's physiological condition (see Porat et al., col. 3, lines 35-61). Porat et al. further teaches embodiments wherein the an implantable biosensor system comprising



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a shunt a having fluid passageway and being operable for draining fluid through a fluid passage way from a portion of the patient body (see Porat et al., col. 3, line 62 through col. 4, line 19), which reads on a reconfigurable sensor, wherein reconfiguration involves reconfiguring a therapeutic reservoir as instantly claimed.

While Porat et al. teaches the activation of the above described implantable, reconfigurable biosensor involving a shunt having a fluid passageway, Porat et al. teaches that the activation of said shunt is based on monitored physiological conditions. Porat et al. does not expressly teach the use of a simulator comprising a system-biology platform and a model to generate a therapeutic or diagnostic output, whereby a biosensor is reconfigured by a simulator.

Giuffre discloses a method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors (e.g., cardiovascular signal) ( See Giuffre, Abstract, col. 4, lines 6-17, and claims 1, 5, 7, 8, 12, and 18). Giuffre discloses generating a signal of a biological target by a biosensor (col. 9, lines 26-37), which reads on a sensor, as recited in claims 36 and 40, and the process step of sensing a biological target to generate a signal, as recited in claim 40. Giuffre discloses a programmable computer systems for simulation of brain activity using a signal data and a model to estimate brain and central nervous system activity (see Giuffre, col. 4, line 6 through col. 5, line 11), which reads on a simulation comprising a system-biology platform, as recited in claims 36 and 40, and the process step of simulating using the signal and a model of the target to generate a therapeutic or diagnostic output, as recited in claim 40. Further, the instant specification is relied upon

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for determining the scope of a "systems-biology platform" (see page 36, line 16-20), as a system that uses software for analyzing computational behavior of a biological system. Giuffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal (see Giuffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59), which reads on a sensor reconfigurable by a simulator, as recited in claims 36 and 40, and the process step of a simulator reconfiguring a sensor, as recited in claim 40.

Giuffre further teaches the detection of drug infusions and drug and alcohol levels in the blood for use in the disclosed method and a system for registering changes in brain and central nervous system activity (see Giuffre, col. 7, line 44 through col. 8, line 2), which reads on a sensor that senses a food material for consumption by a biological target, the generation of a second signal therefrom, and the use of said second signal to generate a therapeutic or diagnostic output as recited claims 37 and 41. Giuffre teaches generating an output according to a regulatory condition by the disclosed simulation system (see Giuffre, col. 7, line 44 through col. 8, line 24), as recited in claims 38 and 42. Giuffre discloses coupling using a trained neural net and self-teaching computer systems (a switch) (see Giuffre, Figs. 1-3 and col. 4, lines 6-60), which reads on a sensor coupled to a simulator via a programmable switch as recited in claims 39 and 43.

Giuffre further teaches the use of separate biosensors for the heart and brain (see Giuffre, col. 4, lines 6-38), which reads on the implantation of a biosensor for the

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heart and brain, as recited in claims 44 and 52, an array of at least two sensors capable of sensing two different biological targets, as recited in claims 45, 46, 49, 53, and 54, and a neural biological target, as recited in claims 47 and 55. Giuffre further teaches that the disclosed method relies upon neurophysiological and cardiovascular monitoring from said biosensors for training a neural network (see Giuffre, col. 3, lines 55-61 and col. 4, lines 6-60). Following the training of a neural network, Giuffre further teaches that only cardiovascular monitoring by heart associated biosensor and the trained neural network are relied upon to estimate the neurophysiological state of a patient (see Giuffre, col. 4, lines 17-38), which reads on the elected species of reconfiguration comprising activating or deactivating at least one biosensor, as recited in claims 48, 49, 51, and 54.

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to combine the biosensor system and methods, set forth by Porat et al., in combination with the method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors, as taught by Giuffre. One of ordinary skill in the art would further be motivated to combine the systems and methods set forth by Porat et al. with that of Giuffre because Giuffre teaches that systems that can predict brain states using already implemented cardiovascular monitoring modalities will allow for predictive capabilities while minimizing risk, cost, and added complexity of such setups (see Giuffre, col. 1, lines 5-25).

***Response to Arguments***

Applicant's arguments filed 10/05/2009 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 103(a) as being unpatentable over Porat et al. in view of Giuffre, applicants argue that the instant claims have been amended to recite a system-biology platform further comprising "computer modeling hardware and software analysis genomics, proteomics, computational chemistry, pharmacogenomics, computational biology, computational biophysics, computational cell behavior, pharmacokinetics, metabolomics, and transcriptomics" to further distinguish the instant claims over the applied prior art of Giuffre.

In response, the recited series of scientific disciplines has not been afforded patentable weight with regard to consideration of the prior art because they do not serve to modify or place any apparent limits on the "systems-biology platform" as instantly claims. See also the above rejections under 35 USC 112, 1st and 2nd paragraphs. Therefore, applicants argument is not persuasive as the systems-biology platform recited in the instant claims is not distinguished over the prior art of record.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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/ERIC S. DEJONG/

Primary Examiner, Art Unit 1631